

**REMARKS**

Claims 1-7 and 9-12 were pending in the instant application. Applicants note that although the Office Action refers to pending claims 1-12, claim 8 had been previously canceled and thus is no longer pending. By this Amendment, Applicants have amended claims 2-9 and 11-12 for clarity. The present Amendment does not introduce any new matter and thus, its entry is respectfully requested. Upon entry of the present Amendment, claims 1-7 and 9-12, as amended will be pending and under examination.

**The December 30, 2005 Office Action**

**Claims rejected under 35 U.S.C. § 112, second paragraph**

Claims 2-9 and 11-12 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. According to the position expressed in the Office Action, claims 2-9 should recite “A resorbable extracellular matrix” (rather than “A matrix”) and claims 11-12 should recite “The scaffold implant” (rather than “The implant”), in order for the claims to have proper antecedent basis.

In response, while Applicants believe the claims are clear as written, to expedite allowance of the application, Applicants have amended claims 2-7, 9 and 11-12 in accordance with the suggestions set forth in the Office Action. In light of these amendments, Applicants respectfully request reconsideration and withdrawal of the rejections.

**Claim rejections under 35 U.S.C. §102**

Claims 1-11 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Stone, et al. (U.S. Pat. No. 5,306,311). Applicants note the statement in the Office Action that claim 8 is a

product-by-process claim and that it will therefore be treated as a product claim and not a method claim. Applicants point out that claim 8 had in fact been canceled in a previous response and its subject matter incorporated into independent claim 1. Applicants therefore assume this statement now applies to claim 1. According to the Office Action, Stone teaches a resorbable implant comprising a resorbable scaffold comprising a porous matrix (abstract). More particularly, in the opinion expressed in the Office Action, Stone teaches the matrix comprising collagen II fibers (columns 2 and 8; Example 2) and polysaccharides including chondroitin sulfates in the amount of about 0=25% by weight (column 3), a pore size range of about 100 to about 400 microns (column 3), a density of about 0.07-0.050 g matrix/cm<sup>3</sup> (column 3), the cartilage may be derived from the condyles of an animal such as a pig (column 8, Example 2), and the height of the implant cylinder is from 0.3-0.6 cm (table 1). According to the Office Action, Stone further teaches a purification process that removes or vastly reduces the non-collagenous materials (column 8). The Office Action further stated that the recited intended use (i.e. “for reconstruction of cartilage tissue”) of a product claim does not alone patentably distinguish the claimed invention over the prior art and that if the prior art structure is capable of performing the intended use, then it meets the claim. The Office Action concluded that the teachings of Stone anticipate the instant claims.

In response, Applicants respectfully traverse the rejection. Applicants’ invention is directed to, *inter alia*, a resorbable extracellular matrix for reconstruction of cartilage tissue, said matrix consisting essentially of a purified collagen II derived from natural cartilage tissue from which non-collagen proteins have been removed, wherein said natural cartilage tissue is subjected to defatting, wherein said matrix consists essentially of fibres of native collagen II which are physiologically acceptable for implant into a mammalian body, said matrix having a pore size within a range of about 50 - 400 µm.

The cited '311 patent does not teach or suggest a resorbable extracellular matrix that consists essentially of a purified collagen II, and does not teach or suggest a matrix whose preparation includes defatting natural cartilage tissue from which collagen II is derived.

The '311 patent refers generally to prosthetic articular cartilage devices which are a dry, porous volume matrix of biocompatible and bioresorbable fibers. The '311 patent, however, discloses only devices requiring both collagen I and collagen II (as well as polysaccharides). Column 8, lines 3-8, states, for example:

In one embodiment, the prosthetic articular cartilage device is constructed mainly of type II collagen matrix *with polysaccharide molecules and type I collagen fibers reinforcing the matrix.*

Alternatively, the device is constructed mainly of type I collagen *with polysaccharides and type II collagen fibers reinforcing the matrix.*  
(Emphasis added).

Therefore, while an alternative device of the '311 patent may contain mainly collagen type II, the device additionally requires both polysaccharides and collagen type I fibers to reinforce the matrix. In contrast, the resorbable extracellular matrix of the present invention requires no such additional reinforcing components to operate effectively in the reconstruction of cartilage tissue. A matrix that requires both of collagen types I and II to be effective (as in the '311 patent) is simply not the same device as one consisting essentially of a purified collagen II and sufficiently effective without the need for a reinforcing amount of collagen type I. For at least this reason, the devices referred to in the '311 patent are not the same as those defined by the present claims and thus, the '311 patent cannot anticipate the present invention.

Moreover, the ‘311 patent does not teach or suggest the feature in the present claims that the natural cartilage tissue (from which the purified collagen type II is derived) is subjected to defatting. As noted in the specification beginning at page 2, line 33, this defatting leaves the collagen II material together with glycosaminoglycans.

In contrast, the ‘311 patent describes distinctly different methods for preparing the Type I and Type II collagen fibers to be used in the described devices. In doing so, it refers to lipid extraction only in connection with the preparation of Type I collagen. See, for example, columns 8 and 9, describing the separate methods in detail. Examples 1 and 2 (columns 11 and 12) further illustrate this distinction between the preparation of the two different types of collagen. Example 1, “Preparation of Purified Type I Collagen” specifically includes a lipid extraction step (step D), while Example 2, “Preparation of Purified Type II Collagen” makes no mention of one. It therefore follows that the Type II collagen present in the device referred to in the ‘311 patent that contains both Type II collagen and a reinforcing amount of Type I collagen, has not been subjected to any defatting as required by the present claims. This omission would necessarily result in a different final product than that claimed in the present invention. Thus, for at least this additional reason, the ‘311 patent cannot anticipate the claims of the present invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-11 under 35 U.S.C. §102(b).

#### Claim rejections under 35 U.S.C. §103

Claims 1-12 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Stone, et al. (‘311) in view of Naughton, et al. (U.S. Patent No. 5,842,477). With respect to the Stone ‘311 patent, the Office Action referred to the comments set forth in connection with the rejection under 35 U.S.C. §102. The Office Action acknowledged that Stone is silent with respect to the teaching of a

material that includes mesenchymal stem cells. According to the Office Action, Naughton teaches a method of repairing cartilage by way of seeding a scaffold with mesenchymal stem cells and implanting it into the cartilage defect. The Office Action concluded on this basis that it would have been obvious for one of ordinary skill in the art to include in Stone a material such as mesenchymal stem cells, as suggested by Naughton.

In response, Applicants respectfully traverse the rejection. Applicants refer to and reiterate the comments made above in connection with the Stone '311 patent and its failure to teach or suggest all limitations of the present claims. The Naughton reference cited in the Office Action does not cure the deficiencies of the Stone '311 patent and thus does not supply the additional teachings necessary to sustain an obviousness rejection. Therefore, any combination of the teachings found in Stone and Naughton fails to teach or suggest the Applicants' presently claimed invention, and thus fails to render obvious present claims 1-12. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-12 under 35 U.S.C. §103.

In view of the above remarks and amendments, Applicants believe that the rejections set forth in the December 30, 2005 Office Action have been fully overcome and that the present application is in condition for allowance. The Office is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

U.S. Application No. 09/988,805  
Reply to Office Action of December 30, 2005  
Amendment dated March 30, 2006

No fee is believed due in connection with the filing of this Amendment. If, however, any fee is deemed necessary, authorization is hereby given to charge such fee, or credit any overpayment, to Deposit Account No. 02-2135.

Respectfully submitted,



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